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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,560	01/29/2004	Mariagrazia Pizza	PP000305.0119	8267
27476 7590 12/05/2007 NOVARTIS VACCINES AND DIAGNOSTICS INC. INTELLECTUAL PROPERTY R338 P.O. BOX 8097 Emeryville, CA 94662-8097			EXAMINER KAM, CHIH MIN	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 12/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/766,560

Applicant(s)

PIZZA ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 07/265,742.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 50 and 53 are pending.

Applicants' amendments filed September 21, 2007 is acknowledged. Applicant's response has been fully considered. Claim 50 has been amended. Therefore, claims 50 and 53 are examined.

Withdrawn Claim Rejections - Obviousness Type Double Patenting

2. The previous rejection of claims 50 and 53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U. S. Patent 6,713,072, is withdrawn in view of applicants' submission of a terminal disclaimer, and applicant's response at page 3 in the amendment filed September 21, 2007.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 50 and 53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 50 and 53 are directed to a method of immunizing a human against pertussis comprising administering an effective amount of a vaccine comprising a therapeutically effective quantity of a polypeptide comprising the S1, S2, S3, S4 and S5 subunits of pertussis toxin, wherein the S1 subunit is modified by direct mutagenesis by the substitution of glutamic acid at position 129 with glycine and the substitution of arginine at position 9 with another natural amino acid such as glycine.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

The specification indicates polypeptides containing the modified S1 subunit are suitable for the preparation of antipertussis vaccine, the preferred are the polypeptides containing at least

one of the S2, S3, S4 and S5 subunits in addition to the modified S1 subunit, particularly preferred polypeptides are the polypeptides having the S2, S3, S4 and S5 subunits with the same arrangement and configuration present in the natural pertussis toxin (paragraphs [66]-[68]). While a single species of the polypeptide having the S1 (modified), S2, S3, S4 and S5 subunits with the same arrangement and configuration present in the natural pertussis toxin as a vaccine has been disclosed, the specification does not describe a genus of variants for polypeptides comprising the S1 (modified), S2, S3, S4 and S5 subunits of pertussis toxin, where the arrangement and configuration of all the subunits in the polypeptide and the effect of the polypeptide as a vaccine are not indicated. Since there is substantial variation in the whole genus of the polypeptide comprising the S1 (modified), S2, S3, S4 and S5 subunits with different arrangement and configuration, one must describe a sufficient variety of species to reflect the variation within the genus according to MPEP § 2163. Without guidance on the correlation of structure to activity of the polypeptide comprising the S1 (modified), S2, S3, S4 and S5 subunits, one skilled in the art would not know which polypeptide can act as a vaccine besides the polypeptide having the configuration of the natural pertussis toxin. The lack of description on the structure to activity correlation of the polypeptides having various arrangements and configurations for the subunits, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Conclusion

4. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

December 4, 2007